

## **REMARKS**

### **I. Introduction**

With the addition herein of new claims 39-43, claims 1 to 43 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

### **II. Rejection of Claims 1 to 5, 21 to 26 and 34 to 38 Under 35 U.S.C. § 102(b)**

Claims 1 to 5, 21 to 26 and 34 to 38 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 6,447,444 ("Avni et al."). Applicant respectfully submits that Avni et al. do not anticipate the present claims for the following reasons.

Claim 1 relates to an orifice introducer device. Claim 1 recites that the orifice introducer device includes a tubular member having a distal end and a proximal end. Claim 1 has been amended herein without prejudice to recite that the distal end includes a slit, a plurality of holes adjacent to the slit and a string through the holes. Claim 1 has been amended herein without prejudice to recite that the distal end is adjustable between a first position for insertion into an orifice and a second position once inserted into the orifice by opening of the slit, wherein the opening of the slit is controlled by moving the string. Support for this amendment may be found, for example, at page 9, lines 10 to 13 of the Specification, which states that "[i]t should be recognized that there are numerous different arrangements that may be employed for lacing the string 22a through the holes 22 at the distal end 21b of the tubular member 21 and for securing the string 22a to an actuation device 20, such as the ring 25, at the proximal end 21a of the tubular member 21."

Claim 21 relates to a method for using an orifice introducer device. Claim 21 recites that the method includes the step of providing a tubular member having a distal end and a proximal end, the distal end being in a first position in which the distal end has a smaller diameter than the proximal end. Claim 21 has been amended herein without prejudice to recite that the distal end includes a slit, a plurality of holes adjacent to the slit and a string through the holes. Claim 21 recites that the method includes the step of inserting the distal end into an orifice. Claim 21 has been amended herein without prejudice to recite that the method includes the

step of adjusting the distal end into a second position by moving the string so as to open the slit. Support for these amendments are set forth above.

Claim 34 relates to an orifice introducer. Claim 34 recites that the orifice introducer includes a tubular sheath having a proximal end and a distal end. Claim 34 has been amended herein without prejudice to recite that the distal end including a slit, a plurality of holes adjacent to the slit and a string through the holes. Claim 34 has been amended herein without prejudice to recite that a diameter of the distal end of the sheath is expandable from a first diameter to a second diameter to allow passage of a surgical instrument having a diameter that is larger than the first diameter by opening of the slit and wherein the opening of the slit is controlled by moving the string. Support for these amendments are set forth above.

Avni et al. purport to describe a video rectoscope. Title. Avni et al. describe that "FIGS. 3A and 3B are schematic, sectional illustrations showing a rectoscope 60 including a disposable sheath 62, in accordance with another preferred embodiment of the present invention." Col. 8, lines 36 to 38. Avni et al. state that "[r]ectoscope 60 includes a generally rigid insertion member 28 with a video camera head 30 at its distal end." Col. 8, lines 36 to 38.

It is respectfully submitted that Avni et al. do not anticipate claims 1, 21 and 34 for at least the reason that Avni et al. do not disclose, or even suggest, all of the features recited in claims 1, 21 and 34. For example, Avni et al. do not disclose, or even suggest, that a distal end of an introducer device is opened by the movement of a string that is positioned within holes adjacent to a slit as recited in claims 1, 21 and 34. The Specification states at page 8, line 13 to 16, that "[t]he distal end 21b of the tubular member 21 includes a longitudinally extending v-shaped opening or slit 21e." The Specification also states at page 9, lines 6 to 9, that "[i]n order to increase the diameter of the distal end 21b of the tubular member 21, the ring 25 may be moved ..., thereby releasing the tension on string 22a." The Specification further states at page 9, lines 10 to 13, that "[i]t should be recognized that there are numerous different arrangements that may be employed for lacing the string 22a through the holes 22 at the distal end 21b of the tubular member 21 and for securing the string 22a to an actuation device 20, such as the ring 25, at the proximal end 21a of the tubular member 21."

Avni et al., on the other hand, state that "[a]s shown in FIG. 3B, after the insertion, leaves 70 are opened to expose window 68 and allow camera head 30

to receive images of the interior of the intestine." Col. 8, lines 54 to 56. Avni et al. further state that "... the leaves are opened by drawing outer layer 64 in a proximal direction, out of the rectum (to the right in FIGS. 3A and 3B), relative to inner layer 66." Col. 8, lines 57 to 59. Thus, even if the spaces between the leaves 70 could be considered slits – which is not conceded – **there are no holes adjacent to the leaves 70 of Avnie et al. nor is there any string positioned within such holes.** Still further, the **opening and closing** of the distal end of the rectoscope in Avni et al. is described as being performed by the outer layer 64 being moved relative to the inner layer 66 such that leaves 70 engage the inner layer 66, and **not by the movement of a string that is positioned within holes adjacent to a slit.**

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Avni et al. does not anticipate claims 1, 21 and 34, because Avni et al. does not disclose, or even suggest, all of the features recited in these claims.

In summary, it is respectfully submitted that Avni et al. do not anticipate claims 1, 21 and 34. As for dependent claims 2 to 5, 22 to 26 and 35 to 38, it is respectfully submitted that Avni et al. does not anticipate these dependent claims for at least the same reasons more fully set forth above.

### **III. Rejection of Claims 11 to 16, 19 to 20, 28 to 29 and 33 Under 35 U.S.C. § 102(b)**

Claims 11 to 16, 19 to 20, 28 to 29 and 33 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 6,167,315 ("Coe et al."). Applicant respectfully submits that Coe et al. does not anticipate the present claims for the following reasons.

Claim 11 relates to an orifice introducer device. Claim 11 recites that the orifice introducer device includes a tubular member having a distal end. Claim 11 recites that the orifice introducer device includes a distal portion having a

proximal end configured to be detachably secured to the distal end of the tubular member. Claim 11 recites that the distal portion is selectively detachable when the orifice introducer device is positioned in the orifice. Claim 11 has been amended herein without prejudice to recite that, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the tubular member. Support for this amendment may be found, for example, at page 11, lines 30 to 31 of the Specification, which states that “[o]nce the distal portion 310 is detached from the distal end 315 of the tubular member 300, the proximal end 310a of the distal portion 310 may contract.”

Claim 28 relates to a method for using an orifice introducer device. Claim 28 recites that the method includes the steps of: providing a tubular member having a distal end; detachably securing a proximal end of a distal portion to the distal end of the tubular member, a distal end of the distal portion having a smaller diameter than the tubular member; inserting the distal end into an orifice; and selectively detaching the distal portion from the tubular member. Claim 28 has been amended herein without prejudice to recite that the method also includes the steps of the distal portion contracting so as to have a diameter smaller than a diameter of the tubular member; and withdrawing the distal portion through the tubular member. Support for this amendment is set forth above in connection with claim 11, and, for example, at page 12, lines 3 to 5, which states that “[t]he tubular insertion device 330 then may be removed from the tubular member 300 by moving it proximally relative to the tubular member 300.”

Coe et al. purport to describe “[a] lead locking device.” Title. Coe et al. state that “a lead locking device... is insertable into a lumen of a lead and which engages and forms a grip with an extended portion of the inner region of the lead.” Col. 2, lines 13 to 16. Coe et al. states that “[t]he mandrel 14 is disposed in the lumen defined by the lead engaging member 12 and attached to the distal tip 24 of the lead engaging member 12.” Col. 6, lines 19 to 21.

It is respectfully submitted that Coe et al. do not anticipate claims 11 and 28 for at least the reason that Coe et al. do not disclose, or even suggest, all of the features recited in claims 11 and 28. For example, Coe et al. do not disclose, or even suggest, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the

tubular member as recited in claims 11 and 28. The Specification states at page 11, line 30 to page 12, line 10, that:

“Once the distal portion 310 is detached from the distal end 315 of the tubular member 300, the proximal end 310a of the distal portion 310 may contract. Advantageously, the proximal end 310a of the distal portion 310 contracts sufficiently such that the outer diameter of the distal portion 310 is smaller than the inside diameter of the tubular member 300. The tubular insertion device 330 then may be removed from the tubular member 300 by moving it proximally relative to the tubular member 300. Moreover, since upon contraction the outer diameter of the distal portion 310 is smaller than the inside diameter of the tubular member, the distal portion 310 may be withdrawn through the tubular member 300 by pulling the string 340 proximally.” Emphasis added.

Coe et al., on the other hand, states that “a lead locking device... is insertable into a lumen of a lead and which engages and forms a grip with an extended portion of the inner region of the lead.” Col. 2, lines 13 to 16. Coe et al. states that:

“The lead locking device 10 may also be unlocked, and removed, from the lead prior to removing the lead from the patient's body. This may be done to abort the operation, remove and reconfigure the lead locking device 10, remove the lead locking device 10 and replace it with another device, or to remove the lead locking device to apply other methods and techniques. To release the lead locking device from the lead, the surgeon slides the inner hypotube 30 and outer hypotube 32 arrangement towards the proximal end, away from the distal tip 24, thus restretching the lead engaging member 12.” Emphasis added.

The Office Action seems to indicate that the distal tip 24 of Coe et al. is considered to be a “distal portion” within the meaning of the present claims (see, for example, Office Action at page 3, which states that “the distal end of the distal portion having a smaller diameter than the rest of the distal end (fig. 2 [24]).” Emphasis added. However, irrespective of this, neither the distal tip 24, nor any other component

of Coe et al., is described as being selectively detached from a tubular member, and which then contracts so as to have a smaller diameter than the tubular member. On the contrary, the distal tip 24 of Coe et al. is described at col. 6, lines 22 to 28, as being formed of metal, suitable to be soldered to the braided sheath that forms the lead engaging member 12. To the extent that any portion of Coe et al. is capable of contracting – which is not conceded – at most the braided sheath/lead engaging member 12 is described as being “restretched” (see col. 9, line 39) but there is no disclosure or suggestion whatsoever that any portion of the braided sheath/lead engaging member 12 is intended for, or even capable of, being selectively detached from a tubular member, nor is intended for, or even capable of, contracting so as to have a smaller diameter than the tubular member.

In summary, it is respectfully submitted that Coe et al. do not anticipate claims 11 and 28.

As for dependent claims 12 to 16, 19 to 20, 29 and 33, it is respectfully submitted that Avni et al. does not anticipate these dependent claims for at least the same reasons more fully set forth above.

#### **IV. Rejection of Claims 1 to 8 Under 35 U.S.C. § 102(b)**

Claims 1 to 8 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 6,599,304 (“Selmon et al.”). Applicant respectfully submits that Selmon et al. does not anticipate the present claims for the following reasons.

Selmon et al. purports to describe “[m]ethods and apparatus for treating vascular occlusions.” Title. Selmon et al. state that “[a]s illustrated in FIGS. 15A-B, for example, distal mounted spreading members 302 may be actuated with an actuating balloon 304 that spreads open the distal end portions 306 of spreading members.” Col. 17, lines 52 to 55. Selmon et al. further state that “[t]he spreading or deflecting members 302 may be deflected in a relatively outward direction by the inflatable actuation balloon 304 disposed within the deflecting member housing 300.” Col. 17, lines 55 to 58.

It is respectfully submitted that Selmon et al. do not anticipate claim 1 for at least the reason that Selmon et al. do not disclose, or even suggest, all of the features recited in claim 1. For example, Selmon do not disclose, or even suggest, that a distal end of an introducer device is opened by the movement of a string that is positioned within holes adjacent to a slit as recited in claim 1. As set forth

above, the Specification states at page 8, line 13 to 16, that “[t]he distal end 21b of the tubular member 21 includes a longitudinally extending v-shaped opening or slit 21e.” The Specification also states at page 9, lines 6 to 9, that “[i]n order to increase the diameter of the distal end 21b of the tubular member 21, the ring 25 may be moved ..., thereby releasing the tension on string 22a.” The Specification further states at page 9, lines 10 to 13, that “[i]t should be recognized that there are numerous different arrangements that may be employed for lacing the string 22a through the holes 22 at the distal end 21b of the tubular member 21 and for securing the string 22a to an actuation device 20, such as the ring 25, at the proximal end 21a of the tubular member 21.”

Selmon et al., on the other hand, states at col. 19, lines 42 to 64, that:

“As shown in FIG. 17B, the upper expansion member 352 may be spread apart or opened so that the distal end 353 of the expansion member is moved laterally with respect to the longitudinal axis of the catheter. The tissue expansion member 352 may be actuated by an attached pull wire 355. The pull wire 355 may be rotatably attached to a relatively proximal portion of the upper expansion member 352 by a pull wire pin and socket assembly 364. ... The flattened distal end section may fit into a corresponding slot or groove formed with corresponding pull wire pin holes in the upper expansion member 352. A pull wire pin 366 may be press fit or otherwise secured in place to hold the pull wire 355 and the upper expansion member 352 together. The upper expansion member 352 may pivot about the hinge pin 362 in response to a directed pulling force to the attached pull wire 355 applied in a relatively proximal direction.”

The Office Action seems to indicate that the hinge pin 366 of Selmon et al. is considered to be a “hole” within the meaning of the present claims (see, for example, Office Action at page 4, which states that “a plurality of holes (fig. 17A and 17B [366]).” Emphasis added. However, irrespective of this, neither the hinge pins 366, nor any other component of Selmon et al., constitute holes that are adjacent to a slit. On the contrary, even if the spaces between the hinged deflecting members 302 of Selmon et al. could be considered slits – which is not conceded – there are no holes adjacent to the hinged deflecting members 302 of Selmon et al. nor is there any string positioned within such holes.

Thus, it is respectfully submitted that Selmon et al. do not anticipate claim 1, because Selmon et al. do not disclose, or even suggest, all of the features recited in these claims. As for dependent claims 2 to 8, it is respectfully submitted that Selmon et al. do not anticipate these dependent claims for at least the same reasons more fully set forth above.

**V. Rejection of Claim 9 and 10 Under 35 U.S.C. § 103(a)**

Claims 9 and 10 were rejected under 35 U.S.C. § 103(a) as unpatentable over Selmon et al. in view of U.S. Patent No. 5,354,302 ("Ko"). It is respectfully submitted that the combination of Selmon et al. and Ko does not render unpatentable claim 14 for at least the following reasons.

Claims 9 and 10 depend from claim 1 and therefore includes all of the features recited in claim 1. As more fully set forth above, Selmon et al. do not disclose, or even suggest, all of the features recited in claim 1, from which claims 9 and 10 depend. Specifically, Selmon do not disclose, or even suggest, that a distal end of an introducer device is opened by the movement of a string that is positioned within holes adjacent to a slit as recited in claim 1. Ko does not disclose or suggest the features recited in claim 1 not disclosed or suggested by the combination of Selmon et al. Accordingly, it is respectfully submitted that the combination of Selmon et al. and Ko does not render unpatentable claims 9 and 10, which depend from claim 1.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

**VI. Rejection of Claim 27 Under 35 U.S.C. § 103(a)**

Claim 27 was rejected under 35 U.S.C. § 103(a) as unpatentable over Avni et al. in view of U.S. Patent No. 5,522,790 ("Moll et al."). It is respectfully submitted that the combination of Anvi et al. and Moll et al. does not render unpatentable claim 27 for at least the following reasons.

Claim 27 has been amended herein without prejudice to depend from claim 21 and therefore includes all of the features recited in claim 21. As more fully set forth above, Avni et al. do not disclose, or even suggest, all of the features recited in claim 21, from which claim 27 depends. Moll et al. do not disclose or suggest the features recited in claim 21 not disclosed or suggested by the

combination of Avni et al. Accordingly, it is respectfully submitted that the combination of Avni et al. and Moll et al. does not render unpatentable claim 27, which depends from claim 21.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

**VII. Rejection of Claims 17 and 18 Under 35 U.S.C. § 103(a)**

Claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as unpatentable over Coe et al. in view of Moll et al. It is respectfully submitted that the combination of Coe et al. and Moll et al. does not render unpatentable claims 17 and 18 for at least the following reasons.

Claims 17 and 18 depend indirectly from claim 11 and therefore includes all of the features recited in claim 11. As more fully set forth above, Coe et al. do not disclose, or even suggest, all of the features recited in claim 11, from which claims 17 and 18 depend. Specifically, Coe et al. do not disclose, or even suggest, that, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the tubular member as recited in claim 11. Moll et al. do not disclose or suggest the features recited in claim a1 not disclosed or suggested by Coe et al. Accordingly, it is respectfully submitted that the combination of Coe et al. and Moll et al. does not render unpatentable claims 17 and 18, which depend from claim 11.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

**VIII. Rejection of Claims 30 to 32 Under 35 U.S.C. § 103(a)**

Claims 30 to 32 were rejected under 35 U.S.C. § 103(a) as unpatentable over Coe et al. in view of Moll et al. As an initial matter, claim 30 has been canceled herein without prejudice, and thus the rejection of claim 30 is considered moot. It is respectfully submitted that the combination of Coe et al. and Moll et al. does not render unpatentable claims 31 to 32 for at least the following reasons.

Claims 31 to 32 depend indirectly from claim 28 and therefore includes all of the features recited in claim 28. As more fully set forth above, Coe et al. do not disclose, or even suggest, all of the features recited in claim 28, from which claims

31 to 32 depend. Specifically, Coe et al. do not disclose, or even suggest, that, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the tubular member as recited in claim 28. Moll et al. do not disclose or suggest the features recited in claim 28 not disclosed or suggested by Coe et al. Accordingly, it is respectfully submitted that the combination of Coe et al. and Moll et al. does not render unpatentable claims 31 to 32, which depend from claim 28.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

#### **IX. New Claims**

New claims 39-43 have been added herein without prejudice. It is respectfully maintained that new claims 39-43 are fully supported by the specification as filed. See, for example, Figures 3A to 3G. Also, it is respectfully submitted that new claims 39-43 are allowable. For example, none of the references cited in the Office Action disclose or suggest that a distal portion is selectively detachable from a tubular member that has a surgical stapler therein by engagement with a second member when the second member is moved longitudinally.

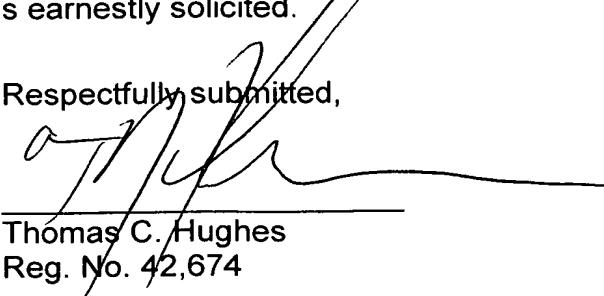
#### **X. Conclusion**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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